

THE CLAIMS

What is claimed is:

1. A method of treating or preventing asthma or  
5 the symptoms thereof in a human which comprises administering  
to a human a therapeutically effective amount of  
norastemizole, or a pharmaceutically acceptable salt thereof,  
and a therapeutically effective amount of a leukotriene  
inhibitor, or a pharmaceutically acceptable salt thereof.
- 10 2. A method of treating or preventing asthma or  
the symptoms thereof in a human which comprises administering  
to a human a composition, said composition comprising (i) a  
therapeutically effective amount of norastemizole, or a  
15 pharmaceutically acceptable salt thereof; (ii) a  
therapeutically effective amount of leukotriene inhibitor, or  
a pharmaceutically acceptable salt thereof, selected from the  
group consisting of 5-lipoxygenase inhibitors, 5-lipoxygenase  
activating protein antagonists, leukotriene receptor  
20 antagonists, and mixtures thereof; and a pharmaceutically  
acceptable carrier or excipient.
3. The method of claim 1, wherein the  
administration of the amount norastemizole, or a  
25 pharmaceutically acceptable salt thereof, and the amount of  
leukotriene inhibitor, or a pharmaceutically acceptable salt  
thereof, avoids the concomitant liability of adverse effects  
associated with the administration of non-sedating  
antihistamines.
- 30 4. The method of claim 2, wherein the  
administration of the amount norastemizole, or a  
pharmaceutically acceptable salt thereof, and the amount of  
leukotriene inhibitor, or a pharmaceutically acceptable salt  
35 thereof, avoids the concomitant liability of adverse effects  
associated with the administration of non-sedating  
antihistamines.

5. The method of claim 1, 2, 3, or 4 wherein the administering further comprises a therapeutically effective amount of a decongestant, or a pharmaceutically acceptable salt thereof.

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6. The method of claim 1 wherein said human has asthma.

7. A method of treating or preventing dermatitis in a human which comprises administering to a human a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof, and a therapeutically effective amount of a leukotriene inhibitor, or a pharmaceutically acceptable salt thereof.

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8. A method of treating or preventing dermatitis in a human which comprises administering to a human a composition, said composition comprising (i) a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof; (ii) a therapeutically effective amount of leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, selected from the group consisting of 5-lipoxygenase inhibitors, 5-lipoxygenase activating protein antagonists, leukotriene receptor antagonists, and mixtures thereof; and a pharmaceutically acceptable carrier or excipient.

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9. The method of claim 7 wherein the administration of the amount norastemizole, or a pharmaceutically acceptable salt thereof, and the amount of leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, avoids the concomitant liability of adverse effects associated with the administration of non-sedating antihistamines.

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10. The method of claim 8 wherein the administration of the amount norastemizole, or a

pharmaceutically acceptable salt thereof, and the amount of leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, avoids the concomitant liability of adverse effects associated with the administration of non-sedating  
5 antihistamines.

11. The method of claim 7, 8, 9, or 10 wherein the administering further comprises a therapeutically effective amount of a decongestant, or a pharmaceutically acceptable  
10 salt thereof.

1 ~~12.~~ A method of treating or preventing allergic rhinitis in a human which comprises administering to a human a therapeutically effective amount of norastemizole, or a  
15 pharmaceutically acceptable salt thereof, and a therapeutically effective amount of a leukotriene inhibitor, or a pharmaceutically acceptable salt thereof. ✓

2 ~~13.~~ A method of treating or preventing allergic  
20 rhinitis in a human which comprises administering to a human a composition, said composition comprising (i) a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof; (ii) a  
therapeutically effective amount of leukotriene inhibitor, or  
25 a pharmaceutically acceptable salt thereof, selected from the group consisting of 5-lipoxygenase inhibitors, 5-lipoxygenase activating protein antagonists, leukotriene receptor antagonists, and mixtures thereof; and a pharmaceutically acceptable carrier or excipient. ✓

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3 ~~14.~~ The method of claim ~~12~~ wherein the administration of the amount norastemizole, or a pharmaceutically acceptable salt thereof, and the amount of leukotriene inhibitor, or a pharmaceutically acceptable salt  
35 thereof, avoids the concomitant liability of adverse effects associated with the administration of non-sedating antihistamines.

4 15. The method of claim <sup>2</sup>13, wherein the administration of the amount norastemizole, or a pharmaceutically acceptable salt thereof, and the amount of leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, avoids the concomitant liability of adverse effects associated with the administration of non-sedating antihistamines.

5 16. The method of claim <sup>1 2 3 4</sup>12, 13, 14, or 15 wherein the administering further comprises a therapeutically effective amount of a decongestant, or a pharmaceutically acceptable salt thereof.

17. A method of treating or preventing inflammation in a human which comprises administering to a human a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof, and a therapeutically effective amount of a leukotriene inhibitor, or a pharmaceutically acceptable salt thereof. ✓

20 18. A method of treating or preventing inflammation in a human which comprises administering to a human a composition, said composition comprising (i) a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof; (ii) a therapeutically effective amount of leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, selected from the group consisting of 5-lipoxygenase inhibitors, 5-lipoxygenase activating protein antagonists, leukotriene receptor antagonists, and mixtures thereof; and a pharmaceutically acceptable carrier or excipient. ✓

19. The method of claim 17 wherein the administration of the amount norastemizole, or a pharmaceutically acceptable salt thereof, and the amount of leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, avoids the concomitant liability of adverse effects

associated with the administration of non-sedating antihistamines.

20. The method of claim 18, wherein the  
5 administration of the amount norastemizole, or a  
pharmaceutically acceptable salt thereof, and the amount of  
leukotriene inhibitor, or a pharmaceutically acceptable salt  
thereof, avoids the concomitant liability of adverse effects  
associated with the administration of non-sedating  
10 antihistamines.

21. The method of claim 17, 18, 19, or 20 wherein  
the administering further comprises a therapeutically  
effective amount of a decongestant, or a pharmaceutically  
15 acceptable salt thereof.

22. A method for treating or preventing a  
condition responsive to leukotriene inhibition which  
comprises administering a therapeutically effective amount of  
20 norastemizole, or a pharmaceutically acceptable salt thereof, ✓  
and a therapeutically effective amount of a leukotriene  
inhibitor, or a pharmaceutically acceptable salt thereof.

23. A method of treating or preventing a condition  
25 responsive to leukotriene inhibition which comprises  
administering to a human a composition, said composition  
comprising (i) a therapeutically effective amount of  
norastemizole, or a pharmaceutically acceptable salt thereof;  
(ii) a therapeutically effective amount of leukotriene  
30 inhibitor, or a pharmaceutically acceptable salt thereof,  
selected from the group consisting of 5-lipoxygenase  
inhibitors, 5-lipoxygenase activating protein antagonists,  
leukotriene receptor antagonists, and mixtures thereof; and  
(iii) a pharmaceutically acceptable carrier or excipient.

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24. The method of claim 22 wherein the  
administration of the amount norastemizole, or a

pharmaceutically acceptable salt thereof, and the amount of leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, avoids the concomitant liability of adverse effects associated with the administration of non-sedating  
5 antihistamines.

25. The method of claim 23, wherein the administration of the amount norastemizole, or a pharmaceutically acceptable salt thereof, and the amount of  
10 leukotriene inhibitor, or a pharmaceutically acceptable salt thereof, avoids the concomitant liability of adverse effects associated with the administration of non-sedating antihistamines.

26. The method of claim 22, 23, 24, or 25 wherein the administering further comprises a therapeutically effective amount of a decongestant, or a pharmaceutically acceptable salt thereof.

27. The method of claim 22 wherein the condition responsive to leukotriene inhibition comprises asthma or a symptom thereof.

28. The method of claim 22 wherein the condition  
25 responsive to leukotriene inhibition comprises an allergic condition.

29. The method of claim 22 wherein the condition responsive to leukotriene inhibition comprises inflammation.

30 <sup>6</sup> ~~30.~~ The method of claim ~~1, 2, 7, 8, 12, 13, 17, 18, 22, or 23~~ wherein the amount of norastemizole administered is from about 1 mg to about 200 mg per day.

~~382~~ <sup>526</sup> 31. The ~~method~~ of claim 30 wherein the amount of norastemizole administered is from about 10 mg to about 100 mg per day.

32. The method of claim 1, 2, 7, 8, 12, 13, 17, 18, 22, or 23 wherein the compositions are administered as a nasal or oral spray.

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Cont 5 33. The method of claim 1, 2, 7, 8, 12, 13, 17, 18, 22, or 23 wherein at least one of the norastemizole and the leukotriene inhibitor is administered as a nasal or oral spray.

10 34. The method of claim 1, 2, 7, 8, 12, 13, 17, 18, 22, or 23 wherein at least one of the norastemizole and the leukotriene inhibitor is administered in an oral solid dosage form.

15 35. The method of claim 3, 9, 14, 19, or 24 wherein the norastemizole is administered as a nasal or oral spray.

20 36. The method of claim 1, 2, 7, 8, 12, 13, 17, 18, 22, or 23 wherein the leukotriene inhibitor is a 5-lipoxygenase inhibitor.

37. The method of claim 36, wherein the 5-lipoxygenase inhibitor is selected from the group consisting of zileuton, docebenone, piripost, ICI-D2318, and mixtures thereof.

38. The method of claim 1, 2, 7, 8, 12, 13, 17, 18, 22, or 23 wherein the leukotriene inhibitor is a 5-lipoxygenase activating protein.

39. The method of claim 38, wherein the 5-lipoxygenase activating protein is selected from the group consisting of MK-591, MK-886, and mixtures thereof.

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B3 40. The method of claim 1, 2, 7, 8, 12, 13, 17, 18, 22, or 23 wherein the leukotriene inhibitor is a leukotriene receptor antagonist.

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5 17 41. The method of claim 40, wherein the leukotriene receptor antagonist is selected from the group consisting of zafirlukast, montelukast, pranlukast, sodium 1-(((R)-(3-(2-(6,7-difluoro-2-quinolinyl)ethynyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)thio)methyl)cyclopropaneacetate;  
10 1-(((1(R)-(3-(2-(2,3-dichlorothieno[3,2-b]pyridin-5-yl)-(E)-ethenyl)phenyl)-3-(2-(1-hydroxy-1-methylethyl)phenyl)propyl)thio)methyl)cyclopropaneacetic acid, and salts and mixtures thereof.

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15 42. A pharmaceutical composition which comprises a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of a leukotriene inhibitor, or a pharmaceutically acceptable salt thereof; and a  
20 pharmaceutically acceptable carrier or excipient.

43. The pharmaceutical composition of claim 42 which further comprises a therapeutically effective amount of a decongestant, or a pharmaceutically acceptable salt  
25 thereof.

44. A pharmaceutical composition which comprises from about 1 mg to about 200 mg of norastemizole, or a pharmaceutically acceptable salt thereof, and from about 20  
30 mg to about 2,500 mg of 5-lipoxygenase inhibitor, or a pharmaceutically acceptable salt thereof.

45. A pharmaceutical composition which comprises from about 1 mg to about 200 mg of norastemizole, or a  
35 pharmaceutically acceptable salt thereof, and from about 20 mg to about 2500 mg of 5-lipoxygenase activating protein antagonist, or a pharmaceutically acceptable salt thereof.



46. A pharmaceutical composition which comprises  
from about 1 mg to about 200 mg of norastemizole, or a  
pharmaceutically acceptable salt thereof, and from about 2 mg  
to about 200 mg of leukotriene receptor antagonist, or a  
5 pharmaceutically acceptable salt thereof.

47. The composition of claim 42, 43, 44, 45, or 46  
administered as a nasal or oral spray.

10 48. The composition of claim 42, 43, 44, 45, or 46  
wherein at least one of the norastemizole and the leukotriene  
inhibitor is administered as a nasal or oral spray.

15 49. The composition of claim 42, 43, 44, 45, or 46  
wherein at least one of the norastemizole and the leukotriene  
inhibitor is administered in an oral solid dosage form.

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